

### **REMARKS/ARGUMENTS**

Reconsideration of the present application is respectfully requested. Claims 8, 11, and 22-36 are canceled herein without prejudice or disclaimer. Claims 1, 9, and 12 have been amended herein. Therefore, claims 1-7, 9-10, and 12-21 are presently pending, with claim 1 being the sole independent claim.

In the specification, amendments have been made to clarify aspects of the present invention that are inherently depicted in the drawings. Applicant respectfully submits that no new matter is being introduced as a result of these amendments. Most notably, the amendments cancel the term "lowermost constricted margin 82" and include the newly added term "distal constricted margin 82." Thus, the amended specification discloses how the main portion 20 and overhanging portion 24 cooperatively present a distal constricted margin 82 of the receptacle 12 positioned adjacent the distal end 22 of the limb.

Applicant respectfully submits that no new matter is being introduced as a result of the amendments to the specification. "By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter." (M.P.E.P. § 2163.07(a)).

Applicant submits that the term "distal constricted margin 82," although newly recited in the written description, is disclosed inherently in the original specification, and inclusion of this

term does not introduce new matter. When the shrinker 10 is donned by the user as shown in original FIG. 1 and the portions 20,24 are folded onto one another, the receptacle 12 necessarily presents a margin (i.e., boundary area) formed by the portions 20,24. Because the original specification discloses that the portion 24 is stretched upward until the ring 26 reaches the distal end 22 of the limb, the margin is adjacent the distal end 22 and is consequently a distal margin. As shown in FIGS. 1 and 4, the sliding-ring 16 cooperates with the receptacle 12 to constrict the margin because the disclosed receptacle 12 extends through the constrictive ring 16. Therefore, the distal margin is constricted. Consequently, Applicant submits that the "distal constricted margin 82" and the other amendments to the specification are fully supported by the original disclosure and the amended specification as a whole includes no new matter. Applicant respectfully requests that the objections to the specification and drawings be withdrawn.

In the Office Action dated April 17, 2008, claims 1 and 22 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. More particularly, the claim limitation "lowermost constricted margin" is asserted to be unclearly associated with the disclosed structure. As discussed above, amendments to the specification cancel the term "lowermost constricted margin 82" and include the newly added term "distal constricted margin 82," which is clearly supported by the original disclosure. Claim 22 has been canceled and independent claim 1 includes the limitation "distal constricted margin." Therefore, Applicant requests that this rejection be withdrawn.

Also in the present Office Action, claims 1-7 and 14-21 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 3,138,156 to Crowell et al. (the "Crowell et al. '156 patent") in view of U.S. Patent No. 3,449,766 to Garber et al. (the "Garber et al. '766 patent") and/or U.S. Patent No. 3,237,210 to Graber (the "Graber '210 patent"). Claims 8-13 and 22-36 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the Crowell et al. '156 patent in view of the Garber et al. '766 patent and/or the Graber '210 patent, and further in view of U.S. Patent No. 6,158,253 to Svoboda et al. However, Applicant respectfully submits that none of the prior art references of record, when considered singly or in combination, show or suggest the use of the structure recited in the claims.

Initially, Applicant submits that a *prima facie* case of obviousness has not been established. The law places upon the Examiner the initial burden of establishing a *prima facie* case of obviousness. *See in re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992). "The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness. If, however, the examiner does produce a *prima facie* case, the burden of coming forward with evidence or arguments shifts to the applicant who may submit additional evidence of nonobviousness." (M.P.E.P. § 2142).

The United States Supreme Court reaffirmed in *KSR International v. Teleflex* the framework for applying the statutory language of 35 U.S.C. § 103 set forth in the landmark case

*Graham v. John Deere Co.*, 383 U.S. 1 (1966). (*KSR*, 550 U.S. at \_\_\_, 82 U.S.P.Q.2d at 1391.). The test is objective and must make the following inquiries:

Under [35 U.S.C.] § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unresolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

(*KSR*, 550 U.S. at \_\_\_, 82 U.S.P.Q.2d at 1391 *quoting* *Graham*, 383 U.S. at 17-18).

If the *Graham* factors are met, the Examiner must "then determine whether the claimed invention would have been obvious to one of ordinary skill in the art." (M.P.E.P. § 2141 III.). The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. (*Id.*). The analysis supporting a rejection under 35 U.S.C. § 103 should be made explicit. (*Id.*). Furthermore, "there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." (*Id.*).

Applicant submits that the Garber et al. '766 patent and Graber '210 patent present nonanalogous art that is not within the scope of the prior art. A determination of the scope and content of the prior art involves distinguishing analogous art from non-analogous art. (*See In re Clay*, 966 F.2d 656, 658 (Fed. Cir. 1992).). To be considered analogous art, a reference must satisfy one of two criteria. (*Id.* at 659-59.). First, a reference is considered analogous if it is within the same field of endeavor as the claimed invention, regardless of the problem addressed. (*Id.*).

Alternatively, even if a reference is not within the inventor's field of endeavor, the reference may still be analogous if it is reasonably pertinent to the particular problem with which the inventor is involved. (*Id.*).

The Garber et al. '766 patent and the Graber '210 patent are cited for their asserted teaching of a vertically movable constricting element. The Garber et al. '766 patent is directed to an article of apparel for use as a head covering or a dickey. Such articles are not in the same field of endeavor and are not pertinent to the problem associated with the present invention, i.e., providing an above-knee shrinker for applying therapeutic compression to a leg residual limb. The article illustrated in the Garber et al. '766 patent would not be capable of providing compression to an amputated limb. The Graber '210 patent is also directed to an article of apparel for use as a muffler or head covering. Similar to the Garber et al. '766 patent, the articles disclosed in the Graber '210 patent are not in the same field of endeavor and are not pertinent to the problem of shrinkers for use on an amputated limb. Thus, a proper *prima facie* case of obviousness has not been established.

Applicant also submits that an explicit reason why the claimed invention would have been obvious has not been articulated. Rather, it is asserted in the Action that the constricting element as disclosed in either the Garber et al. '766 patent or the Graber '210 patent is "capable of being vertically moveable along the receptacle 11 of Crowell et al to adjust a length of the doubled over portion of the receptacle." The determination of obviousness is based, not only on whether a person of ordinary skill in the art would be motivated to combine the references to achieve the claimed invention, but also whether there would have been a reasonable expectation of success in

doing so. *PharmaStem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007) (decided after *KSR*, citing *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1164 (Fed. Cir. 2006)).

Amended independent claim 1 recites, among other things, an above knee shrinker that includes a tubular receptacle, a core-spun fabric construction providing so-called "4-way stretch," a U-shaped opening projecting from the top end of the receptacle, and a constricting element that receives the receptacle to permit doubling over of the receptacle and thereby defining a main tubular portion and a doubled over tubular portion. This particular combination of claimed features enables a shrinker with a number of unexpected advantages. For instance, the inventive shrinker has been found to be surprisingly easier to don than conventional above-knee shrinkers and less painful for users to don. There is no explicit finding in the Action that the combination of features recited in the claimed invention would predictably result in such benefits, as understood by one of ordinary skill in the art having knowledge of the asserted references. Moreover, there is no explicit finding in the Action that a skilled artisan would have been motivated to combine the references to achieve the unexpected advantages resulting from the claimed combination of features. Consequently, a *prima facie* case of obviousness has not been established.

Even if, *arguendo*, a *prima facie* case of obviousness is established, Applicant respectfully submits that such an obviousness rejection would be overcome by secondary considerations.

"If a *prima facie* case of obviousness is established, the burden shifts to the applicant to come forward with arguments and/or evidence to rebut the *prima facie* case." (M.P.E.P. § 2145.).

Rebuttal evidence and arguments can be presented "by way of an affidavit or declaration under 37 CFR 1.132" and "may include evidence of 'secondary considerations,' such as 'commercial success, long felt but unsolved needs, [and] failure of others.'" (*Id.*). This Amendment is accompanied by a Declaration filed pursuant to 37 C.F.R. § 1.132. The Declaration, executed by Mark W.L. Smith, a co-inventor in the present application, attests to secondary considerations of long-felt need and commercial success associated with the present invention.

The Declaration establishes that the industry had a long-felt need for an above-knee shrinker and this need was met by the Knit-Rite Compressogrip Above-knee Shrinker product (the "CGAK Shrinker"), which embodies aspects of the invention claimed in the present application. "For secondary considerations to have probative value, the decision maker must determine whether there is a nexus between the merits of the claimed invention and the secondary considerations." (*Ashland Oil v. Delta Resins & Refractories* 776 F.2d 281, 306 n.42 (Fed. Cir. 1985).). The Declaration explains that conventional above-knee shrinkers have long been difficult for users because the compressive force provided by these shrinkers makes them difficult to stretch and pull onto the amputated limb. Furthermore, the CGAK Shrinker has been attested as being easier to use because the user can pull on one portion at a time. Consequently, the Declaration establishes that the industry had a long-felt need for an above-knee shrinker that provides substantial compression of the amputated limb while being easy to slip onto the limb, and that the claimed invention meets this need.

The Declaration also establishes that the present invention has achieved commercial

success sufficient to preclude an obviousness rejection. "Evidence of commercial success, or other secondary considerations, is only significant if there is a nexus between the claimed invention and the commercial success." (Ormco v. Align Tech., 463 F.3d 1299, 1211-12 (Fed. Cir. 2006).). The Declaration attests to a substantial increase in revenue due to sales of the CGAK Shrinker in the five-year period. In particular, sales revenue of the CGAK Shrinker in 2008 are expected to be about four times greater than sales in 2003. Furthermore, the Declaration states that market share for the CGAK Shrinker has grown from zero to about 33% in the past five years. Yet further, the Declaration illustrates superior market performance of the CGAK Shrinker when compared to other shrinkers offered by Knit-Rite and to overall demand. Over the five-year period, sales revenue of conventional above-knee shrinkers by Knit-Rite decreased by more than half, while revenue for Knit-Rite below-knee shrinkers remained constant. Additionally, Medicare utilization for purchase of above-knee shrinkers steadily declined in the five-year period, indicating that overall market demand for above-knee shrinkers has declined.

However, as stated in the Declaration, Knit-Rite has several competitors in the above-knee shrinker market, with one competitor having about a 60% share of the above-knee shrinker market. Consequently, the superior market performance of the CGAK Shrinker is not attributable to Knit-Rite's market position. Moreover, the Declaration attests that marketing costs for the CGAK Shrinker have been similar to those for other Knit-Rite products. Therefore, the market performance of the CGAK Shrinker is not attributable to Applicant's marketing acumen. Consequently, the Declaration establishes commercial success of the present invention sufficient to rebut a *prima facie*



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case of obviousness. Applicant respectfully requests that the obviousness rejections be withdrawn.

In view of the foregoing, Applicant submits that independent claim 1 recites structure not shown or suggested in the prior art references of record. The dependent claims depend, either directly or indirectly, from claim 1 and recite additional features of the invention not shown or suggested by the prior art.

Therefore, the present application should now be in condition for allowance and such allowance is respectfully requested. Should the Examiner have any questions, please contact the undersigned at (800) 445-3460.

A 3-month Petition for Extension of Time accompanies this Amendment, along with authorization to charge \$555.00 to the undersigned's Deposit Account No. 19-0522 for the petition fee set forth in 37 C.F.R. § 1.17. The Commissioner is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Deposit Account No. 19-0522.

Respectfully submitted,

HOVEY WILLIAMS LLP



By: \_\_\_\_\_

Andrew G. Colombo, Reg. No. 40,565  
10801 Mastin Boulevard, Suite 1000  
Overland Park, Kansas 66210  
(913) 647-9050

ATTORNEYS FOR APPLICANT